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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,653	10/21/2003	Shiping Wang	029714.00054	5864
79439 7590 10/09/2008 Arent Fox LLP and Cardinal Health, Inc. 1050 Connecticut Ave., N.W. Suite 400 Washington, DC 20036				
EXAMINER				
BERNATZ, KEVIN M				
ART UNIT		PAPER NUMBER		
1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/690,653

Applicant(s)

WANG ET AL.

Examiner

Kevin M. Bernatz

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Amendments to claims 18, 34 and 35, filed on August 20, 2008, have been entered in the above-identified application.
2. Applicants' declaration has been considered and is deemed persuasive to antedate the prior art reference Chou (U.S. Patent App. No. 2003/0204893 A1).
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Request for Continued Examination

4. A Request for Continued Examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2008 has been entered. An action on the RCE follows.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 18 – 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33 - 55 of copending Application No. 10/882,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are recognized by the prior art as matters of mere optimization of the coating composition depending on the desired end use (*see art cited in pending rejections, below*). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. Claims 18 – 24, 26, 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soerens et al. (U.S. Patent No. 6,967,261 B1) in view of Hahn et al. (U.S. Patent App. No. 2003/0124202 A1) and/or Murray et al. (U.S. Patent No. 4,920,158). *The Examiner notes that this is substantially the same rejection as in Paragraph No. 8 of the Office Action mailed on July 13, 2007, other than removing any reference to the Chou '893 A1 reference.*

Regarding claims 18, 26 and 27, Soerens et al. disclose an elastomeric article (col. 35, lines 33 – 49: *elastomeric polyisoprene bandage*) comprising an elastomeric layer having a skin contacting surface (col. 7, line 59 bridging col. 8, line 5 and col. 35, lines 33 – 54: *base sheet*); and a coating composition directly on (e.g. Figure 2, element 70 is the elastomeric layer and element 80 is the inventive coating composition – see col. 35, line 33 bridging col. 36, line 11) the skin-contacting surface of said elastomeric layer (col. 5, line 51 bridging col. 6, line 24 and example 18), said coating composition being in a dry state (*ibid* and col. 32, lines 24 – 27; col. 35, line 33 bridging col. 36, line 32; and examples) and comprising at least one polyhydric alcohol moisturizer (examples, especially 18 and 19: *glycerin*), wherein said composition is water-soluble and hydratable upon contact with skin (examples; col. 5, line 51 bridging col. 6, line 24; col. 32, lines 24 – 27; and col. 35, line 33 bridging col. 36, line 32).

Soerens et al. fail to teach adding at least one alphahydroxy lactone to the coating composition, though Soerens et al. does teach that additional additives are envisioned within the scope of the invention (col. 39, lines 22 – 29).

However, Hahn et al. teach that it is known in the art that gluconolactone meeting Applicants' claimed limitations is an exfoliant for therapeutic compositions (*Paragraphs 0002 and 0007*) and Murray et al. teach adding gluconolactone meeting Applicants' claimed limitations to a wound dressing or therapeutic skin coating material (*Title; col. 7, lines 18 – 50; and col. 8, lines 22 – 31*) for use as a drying aid, plasticizer, and/or aesthetic purposes (*col. 6, lines 3 – 9; col. 6, lines 44 – 59; col. 7, lines 9 – 50; col. 8, lines 8 – 21; col. 12, lines 36 – 39; and examples*).

It would therefore have been obvious to one of ordinary skill in the art at the time of the Applicant(s) invention to modify the device of Soerens et al. to include an exfoliant such as gluconolactone in the coating composition as taught by Hahn et al., and/or Murray et al., since such an additive can serve as an exfoliant, a drying aid, a plasticizer or simply for aesthetic purposes.

Regarding claims 19 – 22, the Examiner notes that Soerens et al. disclose elastomeric base sheets (*col. 7, line 59 bridging col. 8, line 5 and col. 35, lines 33 – 54*), wherein the Examiner takes Official Notice that the claimed specific elastomeric materials are known in the art as elastomeric materials useable to make films for skin-contacting articles.

The limitation(s) in claims 23 and 24 are intended use limitation(s) and are not further limiting in so far as the structure of the product is concerned. Note that "in apparatus, article, and composition claims, intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is**

capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art." [emphasis added] *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). See MPEP § 2111.02. In the instant case, the Examiner notes that the disclosed elastomeric coating composition (while in the form of a bandage) could be formed in the form of a glove, if desired.

Regarding claims 29 and 30, Soerens et al. disclose adding film-forming polymers meeting Applicants' claimed limitations (*col. 4, line 22 bridging col. 5, line 28 and examples, especially examples 18 and 19*).

Regarding claim 31, the Examiner deems that disclosed grafted-PEO, which swells upon contact with water, functions as a "hydration promoter" by providing a hydration source within proximity of the skin (*col. 8, lines 45 – 52 and example 19*).

8. Claims 25, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soerens et al. in view of Hahn et al. and/or Murray et al. as applied above, and further in view of Mansouri ('680 A1).

Regarding claims 25 and 28, Soerens et al., Hahn et al. and Murray et al. are relied upon as described above.

None of the above disclose adding pantothenol meeting Applicants' claimed limitations.

However, Mansouri teaches that it is known in the art to add vitamins, including pantothenol (*which the Examiner notes is the provitamin B form per Applicants' specification, page 10, lines 1 - 18*) to skin care lotions in order to provide vitamin enhancement to a person's skin (*Paragraph 0125*).

It would, therefore, have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to modify the device of Soerens et al. in view of Hahn et al. and/or Murray et al. to include pantothenol in provitamin B form as taught by Mansouri, since such an addition is known in the art and would result in vitamin enhancement to a person's skin.

Regarding claim 32, Soerens et al. is deemed to disclose materials which function as plasticizers (*col. 8, lines 45 – 52; examples 18 and 19: grafted-PEO and polymeric gels*).

9. Claims 18 – 29 and 31 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou (U.S. Patent No. 6,953,582 B2) in view of Mansouri ('680 A1) and Hahn et al. ('202 A1) and/or Murray et al. ('158) and further in view of Applicants' admissions. *The Examiner notes that this is substantially the same rejection as in Paragraph No. 13 of the Office Action mailed on July 13, 2007, other than removing any reference to the Chou '893 A1 reference.*

Regarding claims 18, 26 and 27, Chou '582 B2 discloses an elastomeric article (*Title; Abstract; col. 1, line 16 bridging col. 2, line 16; and col. 3, lines 44 - 53*) comprising an elastomeric layer having a skin contacting surface (*ibid*); and a coating

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composition directly on (see *Figure 5*) the skin-contacting surface of said elastomeric layer (*ibid*), said coating composition being in a dry state (*ibid*), wherein said composition is water-soluble and hydratable upon contact with skin (*ibid*).

Chou '582 B2 fails to teach adding at least one polyhydric alcohol to the coating composition, though Chou '582 B2 does teach that additional additives are envisioned within the scope of the invention (*col. 8, lines 23 - 34*).

However, Mansouri teaches that it is known in the art to add polyhydric alcohol to a coating composition as either a anti-microbial agent or as a humectant (*Paragraphs 0029, 0030, 0061 – 0069: sorbitol and/or glycerin*).

It would, therefore, have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to modify the device of Chou '582 B2 to include a polyhydric alcohol meeting Applicants' claimed limitations as taught by Mansouri, since such a component can function as either, or both, of an anti-microbial agent and/or a humectant.

Neither Chou '582 B2 nor Mansouri teach adding at least one alphahydroxy lactone to the coating composition, though Chou '582 B2 does teach that additional additives are envisioned within the scope of the invention (*col. 8, lines 23 - 34*).

However, Hahn et al. teach that it is known in the art that gluconolactone meeting Applicants' claimed limitations is an exfoliants for therapeutic compositions (*Paragraphs 0002 and 0007*) and Murray et al. teach adding gluconolactone meeting Applicants' claimed limitations to a wound dressing or therapeutic skin coating material (*Title; col. 7, lines 18 – 50; and col. 8, lines 22 - 31*) for use as a drying aid, plasticizer, and/or

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aesthetic purposes (*col. 6, lines 3 – 9; col. 6, lines 44 – 59; col. 7, lines 9 – 50; col. 8, lines 8 – 21; col. 12, lines 36 – 39; and examples*).

It would therefore have been obvious to one of ordinary skill in the art at the time of the Applicant(s) invention to modify the device of Chou '582 B2 in view of Mansouri to include an exfoliants such as gluconolactone in the coating composition as taught by Hahn et al., and/or Murray et al., since such an additive can serve as an exfoliants, a drying aid, a plasticizer or simply for aesthetic purposes.

Regarding claims 19 – 22, the Examiner notes that Chou '582 B2 disclose elastomeric base sheets including natural rubber, etc. (*Title; Abstract; col. 1, line 16 bridging col. 2, line 16; and col. 3, lines 44 - 53*), wherein the Examiner takes Official Notice that the claimed specific elastomeric materials are known in the art as elastomeric materials useable to make films for skin-contacting articles.

The limitation(s) in claims 23 and 24 are intended use limitation(s) and are not further limiting in so far as the structure of the product is concerned. Note that "in apparatus, article, and composition claims, intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. ***If the prior art structure is capable of performing the intended use, then it meets the claim.*** In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art." [emphasis added] *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). See MPEP § 2111.02. In the instant case, the Examiner notes that Chou '582 B2

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disclose forming the article into gloves (*Figures*) and the exact use of the glove is deemed to be an intended use limitation.

Regarding claims 25 and 28, Mansouri teaches that it is known in the art to add both glycerin vitamins, including pantothenol (*which the Examiner notes is the provitamin B form per Applicants' specification, page 10, lines 1 - 18*) to skin care lotions in order to provide vitamin enhancement to a person's skin (*Paragraph 0125*).

Regarding claim 29, Mansouri disclose adding film-forming polymers meeting Applicants' claimed limitations (*Paragraphs 0121 - 0122*).

Regarding claim 31, Mansouri disclose hydration promoters as additives to the coating composition (*Paragraph 0129 - 0130: where citric acid, a.k.a. sodium citrate, is admitted by Applicants' as a known hydration promoter, see specification page 13*).

Regarding claim 32, Mansouri disclose adding materials which are deemed to function as a plasticizer/viscosity enhancer (*Paragraphs 0121-0122*).

Regarding claim 33, the Examiner deems that it would have been obvious to one having ordinary skill in the art to have determined the optimum value of a results effective variable such as the amount of each compound added to the coating through routine experimentation, especially given the teaching in Mansouri regarding the amount of the various additives used in skin care compositions (*examples*) and Murray et al. regarding the use of relatively small concentrations of polyhydric alcohol (*glycerin*) and alphahydroxy lactone (*gluconolactone*) in formation of skin-contacting material (*col. 7, lines 18 - 50 and examples*). *In re Boesch*, 205 USPQ 215 (CCPA 1980); *In re*

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Geisler, 116 F. 3d 1465, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); *In re Aller*, 220 F.2d, 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 34 and 35, these claims are met for the reasons noted above with regard to claims 18, 23 and 24.

10. Claims 30 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou '582 B2 in view of Mansouri and Hahn et al. and/or Murray et al. as applied above, and further in view of Soerens et al. (261 B1).

Chou '582 B2, Mansouri, Hahn et al. and Murray et al. are relied upon as described above.

None of the above disclose adding chitosan to the coating composition.

However, Soerens et al. teach that chitosan is preferably added as a naturally occurring anti-microbial agent (*col. 4, line 22 bridging col. 6, line 24 and examples*). It would, therefore, have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to modify the device of Chou '582 B2 in view of Hahn et al. and/or Murray et al. to include chitosan in the coating composition as taught by Soerens et al., since chitosan is known to be an additive in skin-contacting coatings as a naturally occurring anti-microbial agent.

Response to Arguments

11. The Double Patenting rejection of claims 18 - 36 in view of App '580

No arguments were presented.

12. The rejection of claims 18 - 32 under 35 U.S.C § 103(a) – Soerens et al., in view of various references

Applicant(s) argue(s) that applying moisturizing agents "onto the elastomeric portion of the bandage would adversely affect the ability of the bandage to adhere to the skin, thereby rendering it ineffective for its intended use" (*page 8 of response*). The Examiner respectfully disagrees.

The Examiner notes that the specification is not the measure of the invention. Therefore, limitations contained therein can not be read into the claims for the purpose of avoiding prior art. *In re Sporck*, 55 CCPA 743, 386 F.2d 924, 155 USPQ 687 (1968). It appears that Applicants are reading the claims as if the coating composition must be applied over the *entirety* of the elastomeric surface. This is **not** correct. The claims are open to a partial coverage of the elastomeric layer, as exemplified by Figure 2 of Soerens et al. (*where they note that the absorption pad/coating is formed of the inventive PEO compound – see present rejection of record*). The Examiner further notes that the absorption pad is clearly a *dry* coating layer.

13. The prior rejection under 35 U.S.C § 103(a) – Chou ('893 A1) in view of various references

The above noted rejection has been withdrawn in view of Applicants' arguments, which have been found persuasive. Specifically, Applicant(s) have provided sufficient evidence that Chou ('893 A1) fails to qualify as prior art due to a successful conception and reduction to practice, as evidenced by the Declarations of Shiping Wang, Yun-Suing Tony Yeh, and Wei Cheong Wong (*pages 8 – 10 of response*).

14. The rejection of claims 18 - 36 under 35 U.S.C § 103(a) – Chou '582 B2, in view of various references

First, Applicants argue each reference individually (*pages 11 – 12 of response*). However, Applicant(s) are reminded that "the test for obviousness is not whether features of the secondary reference may be bodily incorporated into the primary reference's structure, nor whether the claimed invention is expressly suggested in any one or all of the references, rather the test is what the combined teachings would have suggested to those of ordinary skill in the art." *Ex parte Martin* 215 USPQ 543, 544 (PO BdPatApp 1981). In the instant case, the Examiner has provided proper motivation statements as to why the *combined* teachings would render the claimed invention obvious.

Next, Applicant(s) argue(s) that the combination is improper for at least two reasons. First, Applicants argue that Hahn et al. teach away from the claimed invention (*pages 11 – 12 of response*). The Examiner respectfully disagrees.

The Examiner notes that Hahn et al. *specifically* is designed for formulations that include an exfoliant and the anti-irritant in combination (*see Paragraph 0106 in Hahn et al., along with Paragraphs 0011 and 0060*). Specifically, Hahn et al. provides an explicit embodiment using both the divalent strontium cation anti-irritant in combination with an exfoliant (*i.e. lactic acid*) and shows that it effectively eliminate skin irritation (*see Paragraph 0104*). As such, the Examiner does not find Applicants' argument convincing that Hahn et al. teach away from the claimed combination. Furthermore, the Examiner notes that Applicants' claims are open (*e.g. "said coating composition ... comprising"*) to additional elements being present, such as the disclosed strontium cations.

Second, Applicants argue that Murray et al. is not analogous to the presently-coated gloves having a dry coating composition that is water soluble (*page 12 of response*). The Examiner respectfully disagrees and notes that Murray et al. was relied upon as supporting evidence teaching that one of ordinary skill in the elastomeric arts would appreciate that gluconolactone can be added to therapeutic skin coating compositions, as well as wound dressings. The Examiner notes that Chou ('582) discloses therapeutic coatings, as does Hahn et al., which leads the Examiner to deem that Murray et al. is directly analogous to the *relied upon* prior art.

Finally, Applicants repeat the arguments against Soerens et al. (*pages 12 - 13 of response*), which are rebutted by the Examiner's comments in Paragraph No. 13, above.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin M. Bernatz whose telephone number is (571) 272-1505. The Examiner can normally be reached on M-F, 8:30 AM - 5:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kevin M Bernatz, PhD/
Primary Examiner, Art Unit 1794

October 7, 2008